

## Suggested Format for Residue Chemistry Study Reports

# Confined Accumulation in Rotational Crops

## OPPTS 860.1850

The purpose of this document is to suggest the format for final reports (right column) and to provide instructions for creation of Adobe PDF electronic submission documents (left column). The format is modeled after the NAFTA Data Evaluation Record template that will be used by OPP's and PMRA's scientists when this type of study is reviewed. The format is in outline form. The study report will include text and standard tables (detailed below).

Regarding PDF, both 'bookmarks' and 'links' are referenced. Bookmarks and links are similar in function in that both provide the reader with a way to move efficiently through a document as well as across documents. Bookmarks are a type of link that appear in the navigation pane on the left side of the PDF Reader user screen. Links appear within the body of a document as blue text. They permit the reader to jump to other locations with related information in the same document or other electronic documents.

| Residue Chemistry Study Reports –<br>CONFINED ACCUMULATION IN ROTATIONAL CROPS            |   |
|---|---|
| Instructions to create PDF  | Document Format   |
| Create Bookmarks for each item in Document Format column.                                 | <ul style="list-style-type: none"> <li>• Study Title Page. <ul style="list-style-type: none"> <li>- Statement of Data Confidentiality<br/><i>No confidentiality claims can be made for electronically submitted studies at this time.</i></li> </ul> </li> <li>• GLP Statement.</li> <li>• QA Statement.</li> <li>• Table of Contents.</li> </ul> |
| Create links in summary to related text and tables in body of study report or appendices. | <ul style="list-style-type: none"> <li>• Executive Summary. <ul style="list-style-type: none"> <li>- Summary of Background Information &amp; Experimental Design.</li> <li>- Summary of Results</li> </ul> </li> </ul>  |
| Create links to related tables.   | <ul style="list-style-type: none"> <li>• Background Information and Experimental Design. <ul style="list-style-type: none"> <li>- Background Information – See Tables 1 and 2.</li> <li>- Experimental Design – See Tables 3 - 6.</li> <li>- Analytical Methodology.</li> </ul> </li> <li>• Results and Discussion – See Tables 7 - 11</li> </ul> |

**Table Formats**

Tables should be imported into the PDF document from their native formats. See OPP's detailed technical specifications for creating PDF for details.

**Table 1 – Test Compound Nomenclature.**

| Compound                  | Chemical Structure |
|---------------------------|--------------------|
|                           |                    |
| Common name               |                    |
| Company experimental name |                    |
| IUPAC name                |                    |
| CAS name                  |                    |
| CAS #                     |                    |
| End-use product / EP      |                    |

**Table 2 – Physicochemical Properties.**

| Parameter  | Value | Reference |
|--|-------|-----------|
| Melting point/range  |       |           |
| pH   |       |           |
| Density  |       |           |
| Water solubility ( __ °C)                                  |       |           |
| Solvent solubility (mg/L at __ °C)                         |       |           |
| Vapor pressure at __ °C                                    |       |           |
| Dissociation constant (pK <sub>a</sub> )                   |       |           |
| Octanol/water partition coefficient Log (K <sub>ow</sub> ) |       |           |
| UV/visible absorption spectrum                             |       |           |

**Table 3 – Test Site and Crop Information.**

| Testing Environment* | Soil Characteristics |      |    |     | Environmental Conditions |          |
|----------------------|----------------------|------|----|-----|--------------------------|----------|
|                      | Type                 | % OM | pH | CEC | Temperature              | Rainfall |
|                      |                      |      |    |     |                          |          |
|                      |                      |      |    |     |                          |          |

\* outdoor test plots, greenhouse, plant growth chambers, etc.

**Table 4 – Crop Information.**

| Crop/crop group | Variety | Plant-back intervals (days) | Growth stage at harvest | Harvested RAC | Harvesting procedure |
|-----------------|---------|-----------------------------|-------------------------|---------------|----------------------|
|                 |         |                             |                         |               |                      |
|                 |         |                             |                         |               |                      |

**Table 5 – Test Material Characteristics.**

|                               |                    |                    |
|-------------------------------|--------------------|--------------------|
| <b>Chemical structure</b>     | [Insert structure] | [Insert structure] |
| <b>Radiolabel position</b>    |                    |                    |
| <b>Lot No.</b>                |                    |                    |
| <b>Purity</b>                 |                    |                    |
| <b>Specific activity (Bq)</b> |                    |                    |
| <b>Code</b>                   |                    |                    |

**Table 6 – Use Pattern Information.**

|                               |  |
|-------------------------------|--|
| <b>Chemical name</b>          |  |
| <b>Application method</b>     |  |
| <b>Application rate</b>       |  |
| <b>Number of applications</b> |  |
| <b>Timing of applications</b> |  |
| <b>PHI</b>                    |  |

**Table 7 – Summary of Storage Conditions.**

| <b>Matrix<br/>(RAC or Extract)</b> | <b>Plant-back<br/>interval (days)</b> | <b>Storage<br/>temp. (°C)</b> | <b>Actual storage<br/>duration<br/>(days or months)</b> | <b>Limit of demonstrated<br/>storage stability<br/>(days or months)</b> |
|------------------------------------|---------------------------------------|-------------------------------|---|---|
|                                    |                                       |                               |   |   |
|                                    |                                       |                               |   |   |

**Table 8 – Total Radioactive Residues (TRRs) in [*matrices*].**

| <b>Matrix</b>         | <b>Plant-back<br/>interval (days)</b> | <b>Aa-label</b> |            | <b>Bb-label</b> |            |
|-----------------------|---------------------------------------|-----------------|------------|-----------------|------------|
|                       |                                       | <b>% TRR</b>    | <b>ppm</b> | <b>% TRR</b>    | <b>ppm</b> |
|                       |                                       |                 |            |                 |            |
|                       |                                       |                 |            |                 |            |
| <b>Total recovery</b> |                                       |                 |            |                 |            |

**Table 9 – Distribution of the Parent and the Metabolites in Rotational Crop Matrices when Dosed with <sup>14</sup>C-labeled [chemical]**

[Note: Add rows to the table as needed to accommodate the fractionation/characterization scheme. Create additional tables as needed for each plant-back interval and to accommodate additional radiolabel positions.]

| Metabolite Fraction   | Matrix 1       |     | Matrix 2       |     | Matrix 3       |     |
|---|----------------|-----|----------------|-----|----------------|-----|
|   | (TRR = xx ppm) |     | (TRR = xx ppm) |     | (TRR = xx ppm) |     |
|   | % TRR          | ppm | % TRR          | ppm | % TRR          | ppm |
| <b>Surface wash</b>   |                |     |                |     |                |     |
| [Add a row for each identified compound]                      |                |     |                |     |                |     |
| [Unidentified compound]                                       |                |     |                |     |                |     |
| <b>Organosoluble</b>  |                |     |                |     |                |     |
| [Add row for each identified compound]                        |                |     |                |     |                |     |
| [Unidentified compound]                                       |                |     |                |     |                |     |
| <b>Aqueous soluble</b>  |                |     |                |     |                |     |
| [Add row for each identified compound]                        |                |     |                |     |                |     |
| [Unidentified compound]                                       |                |     |                |     |                |     |
| <b>Total extractable (Aqueous + organic)</b>                  |                |     |                |     |                |     |
| <b>Total identified</b>                                       |                |     |                |     |                |     |
| <b>Total unidentified</b>                                     |                |     |                |     |                |     |
| <b>Total bound residues (PES)</b>                             |                |     |                |     |                |     |
| <b>% Accountability</b><br><b>Total (ppm)/TRR (ppm) × 100</b> |                |     |                |     |                |     |

**Table 10 – Summary of Characterization and Identification of Radioactive Residues in Rotational Crop Matrices Following Application of Radiolabeled [chemical] at [rate].**

[Note: Create additional tables for each plant-back interval and as needed to accommodate additional radiolabel positions.]

| Compound                   | Matrix 1 |     | Matrix 2 |     | Matrix 3 |     |
|----------------------------|----------|-----|----------|-----|----------|-----|
|                            | % TRR    | ppm | % TRR    | ppm | % TRR    | ppm |
| [Parent]                   |          |     |          |     |          |     |
| [Metabolite 1]             |          |     |          |     |          |     |
| [Metabolite 2]             |          |     |          |     |          |     |
| [Metabolite 3]             |          |     |          |     |          |     |
| [Metabolite 4]             |          |     |          |     |          |     |
| <b>Total identified</b>    |          |     |          |     |          |     |
| <b>Total characterized</b> |          |     |          |     |          |     |
| <b>Total extractable</b>   |          |     |          |     |          |     |
| <b>Total bound</b>         |          |     |          |     |          |     |

**Table 11 – Identification of Compounds from the Confined Rotational Crop Study.**

| Common name/code | Chemical name | Chemical structure |
|------------------|---------------|--------------------|
|                  |               |                    |
|                  |               |                    |